

## DEPARTMENT OF THE ARMY

OFFICE OF THE SURGEON GENERAL WASHINGTON, D.C. 20310

REPLY TO ATTENTION OF

SGRD-HR

2 January 1980

SUBJECT: Minutes of Meeting of the Ad Hoc Subcommittee of The Surgeon General's Human Subjects Research Review Board - 20 November 1979

The Surgeon General Headquarters, Department of the Army Washington, DC 20310

1. Under provisions of AR 70-25 and OTSG Reg 15-2, a special meeting of an Ad Hoc Subcommittee of the Human Subjects Research Review Board (HSRRB) was convened at 0900 hours in Room 3E368 in the Pentagon on 20 November 1979 to consider human use issues represented in protocols presented by SRI International [Proposed Grill Flame Protocol: Task II (U) PDSIILPLFRRHONREPNTS (U) - 15 November 1979] and the US Army Missile Command (MICOM) [RPT (U) - 7 November 1979].

## Members present were:

- COL Edward L. Buescher, MC, Chairman, HSRRB
- COL Harry Holloway, MC, Professor and Chairman, Department of Psychiatry, USUHS, Ad Hoc Member, HSRRB
- Dr. K. C. Emerson, Ph.D., Consultant Ad Hoc Member, HSRRB
- Dr. Herbert L. Ley, M.D., Consultant Ad Hoc Member, HSRRB
- "Dr. Chris J. D. Zarafonetis, M.D., Consultant Ad Hoc Member, HSRRB
- Ms. Annie L. Young, Systems Analyst, AMSAA, Ad Hoc Member, HSRRB
- LTC Richard W. Severson, MSC, C, Human Use Review Office, USAMRDC, Recorder
- CPT (P) Steven M. Porter, JAGC, Judge Advocate, USAMRDC, and Member, HSRRB
  - b. Observers/Investigators present were:
- Dr. Billy Z. Jenkins, Ph.D., Grill Flame Principal Investigator, USAMICOM
- Dr. Edward May, Ph.D., Grill Flame Project Leader, SRI International,
- ... Menlo Park, CA (contractor)
- Dr. Hal Puthoff, Ph.D., SRI International, Menlo Park, CA
- Dr. Russell Targ, Ph.D., SRI International, Menlo Park, CA
- Mr. John Kramar, Assistant Director, Army Materiel Systems Analysis Activity, Aberdeen Proving Ground, MD

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- 2. Mr. Kramar presented a resume of the progress to date on the AMSAA Grill Flame Protocol [PBAAADREVGPL] (U) 23 March 1979] dealing with phenomenological validation of technology to be transferred by SRI. The AMSAA effort began in March 1979. The following summarized committee views of the review and discussions:
- a. The study has accomplished the initial objective outlined in Protocol PBAAADREVGPL (U) 23 March 1979 and is now exploring new issues. It is clearly exceeding the validation of technology, and appears to be beyond the work scope originally examined by HSRRB and approved by TSG. The basis for this expanded scope is unclear and the current effort appears to involve human experimentation. The concerns of the ad hoc subcommittee as detailed in the previous minutes are now more relevant: "Army sponsors and action agencies are presently unprepared to address all anticipated problems. Specifically, the concerns include: (1) provision for adequate scientific review of research protocols, (2) provision for collaborating behavioral scientists in execution of protocols, and (3) provision for credible Human Use Review processes or committees in action agencies for review of protocols."
  - b. There clearly is no fixed and formally appointed professional oversight for work being done under "Grill Flame"; rather, oversight appears to be ad hoc, incomplete and by multiple groups, resulting in inadequate continuing assessment. Conclusions and decisions based on data generated from the research will be divergent, depending on which ad hoc group is evaluating the data; evaluating emerging evidence and deciding which evidence is worth pursuing will be an uncoordinated effort.
- c. The subcommittee recommends the ad hoc supervision of the 'Grill Flame program be discontinued and the command responsibility for the program be identified.
  - 3. Dr. May presented the SRI International protocol to the Ad Hoc Subcommittee. Dr. Jenkins presented the MICOM variations of the same protocol. Subsequent to discussions, the following is the unanimous consensus of the subcommittee members:
- a. The SRI International and MICOM protocols do indeed constitute research involving human subjects. The immediate risks to the subjects appear to be minimal; however, there are potential latent related effects which deserve explanation in the subject consent form. Recommend the consent form be amended to include:

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- (1) "You may lose the esteem or respect from certain colleagues because of the nature of Grill Flame activities since some may consider participation in such activities as indicating a belief in the occult or magical. To the knowledge of the investigators no-one has suffered such career damage from a Grill Flame-related activity, but the potential for such is brought to your attention.
- (2) "Some participating subjects may come to believe that they can possess the capacity to use \_\_\_\_\_ and/or \_\_\_ powers for personal profit in risk-taking situations (Example: participating in games of chance or speculative investment). Some individuals who have served as subjects in this kind of experiment have acted on such assumptions to their apparent disadvantage. Thus, the risk exists that you may come to believe that you have a power that you do not possess. You are advised-of this risk and warned that you assume responsibility for any assumptions which you make about your personal powers or capacities."
- b. The concerns expressed in the minutes of 29 March 1979 (ref. paragraph 2a above) concerning the Grill Flame program are also appropriate for these protocols and should be addressed. Responsibility seems to be divided between multiple principal investigators and direction of the program is vague and needs definition. The reviewing subcommittee felt the Army sponsors and action agencies should address the following concerning the Grill Flame program because of the public and political sensitivity of human subjects participating in such a classified project:
  - (1) Scientific review.
- (2) Command and control of the Grill Flame program needs to be delineated and liability concerns properly addressed.
- (3) Public Information Offices for DA and DoD need to be knowledgeable of the ongoing and proposed work.
- (4) The Chain of Command (and responsibility) for the Grill Flame program (this protocol) from DA to DoD needs to be identified.
- (5) Security classification of the studies under the Grill Flame program is perceived to be a major impediment to continued credible scientific pursuit. If the actual R&D effort is biomedical/behavioral science, as it has been published in the open literature, the need for classification is in question. Classification of the military application of the specific science would seem appropriate.

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- 4. In addition, it was recommended that pregnant women should be excluded from participation in the work carried out under this protocol. This recommendation is in keeping with the generally prudent policy of excluding any group of subjects that might be especially sensitive to the effects of stress.
- 5. The ad hoc subcommittee recommends approval of the protocols pending receipt of a new revised consent form which addresses the anticipated risks mentioned above.
- 6. There being no further business, the meeting was adjourned at 1550 hours.

RICHARD W. SEVERSON

LTC, MSC Recorder

APPROVED/DISAPPROVED:

APPROVED/DISAPPROVED:

EDWARD L. BUESCHER

Colonel, MC

Chairman, Human Subjects

Research Review Board

CHARLES C. PIXLEY

Lieutenant General

The Surgeon General